HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M2484n

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

March 12, 1999

WL-25-9

WARNING LETTER

Michael Nassar
Chairman of the Board
Nassmith Pharmaceuticals, Inc.
2515 Industry Street
Oceanside, CA 92054

Dear Mr. Nassar:

During an inspection of your pharmaceutical manufacturing facility conducted on February 9 to 18, 1999, our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). Such deviations cause human drugs manufactured by your company to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (Act).

Our investigation revealed there is no assurance that the methods used in or the facilities and controls used for the manufacture, processing, packing, or holding of your finished pharmaceuticals are in conformance with the GMP requirements as follows:

1. Failure to conduct laboratory determinations of satisfactory conformance to final specifications for drug products, including the identity and strength of each active ingredient, prior to release [21 CFR 211.165]. Specifically, your firm failed to conduct any laboratory tests of your Sinucheck capsules, Aller Clear capsules and Ballistic tables to determine their conformance to their final specifications.

2. Failure to ensure that drug product components are tested for conformity with all appropriate specifications for purity, strength, and quality [21 CFR 211.84(d)(2)]. Specifically, your firm failed to conduct any laboratory testing of pseudoephedrine HCL, ephedrine HCL, and guaifenesin components used in the production of your finished products or obtain a report of analysis from the supplier and conduct at least one specific identity test of the components.

3. Failure to conduct investigation(s) of drug products not conforming with their final specifications [21 CFR 211.192].

Specifically, your firm failed to conduct an investigation of the analytical findings which determined that your Ballistic tablets, Lot No. 1298-21, failed to comply with its specific potency requirements for ephedrine HCL and guaifenesin.

4. Failure to establish and control written production and process control procedures to ensure proper execution of various production and process control functions [21 CFR 211.100]. Specifically, your firm has no documented evidence which provides a high degree of assurance that your production processes for your drug products will consistently produce products meeting their pre-determined specifications and quality attributes, traditionally termed process validation.

5. Failure to establish a written testing program designed to assess the stability characteristics of your drug products [21 CFR 211.166]. Specifically, your firm has not conducted any stability tests to support the two year expiration dates assigned to your drug products.

6. Failure to establish procedures to assure equipment and utensils are sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of drugs beyond the official or other established requirements [21 CFR 211.67]. Specifically, your firm has no documented evidence demonstrating that the sanitizing processes used to clean production equipment and areas are valid and that all residues have been reduced to acceptable levels.

7. Failure to ensure that equipment used in the manufacture, processing, packing, or holding of drug products are designed and/or selected so that product specifications are consistently achieved [21 CFR 211.63]. Specifically, your firm has no documented evidence demonstrating that your process equipment and ancillary systems are capable of consistently operating within their established limits and tolerances.

8. Failure to ensure that employees are capable of performing their assigned functions which are commensurate with their intended duties and are familiar with the Good Manufacturing Practice (GMP) regulation [21 CFR 211.25]. Specifically, your firm has no documented evidence of any training received or written description of your production employees.

9. Failure to maintain a complete record of all information relating to the production and control of each batch of drug products [21 CFR 211.188]. Specifically, your firm's batch

production records contain no information regarding the major equipment used for drug processing, in-process specifications, tableting or encapsulation specifications, complete processing instructions, in-process and finished product sampling testing procedures, and statement of theoretical yields.

The above listed violations are not intended to be construed as all inclusive of those existing at your firm. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder are being met.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes, but is not limited to, seizure and/or injunction. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you plan to take to assure that each of the noted violations will be corrected. Your response should also include an explanation of the specific steps which will be taken to prevent the recurrence of similar violations.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,

Elaine C. Messa
District Director

State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street
PO Box 942732
Sacramento, CA 94234